Original Article

Effect of soy drink replacement in a weight reducing diet on anthropometric values and blood pressure among overweight and obese female youths

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Background: Soy drink replacement in the diet might have beneficial effects on anthropometric and blood pressure values for overweight and obese subjects. Therefore, we are going to determine the effects of soy drink replacements on the weight, waist circumference and blood pressure among overweight and obese female youths. Patients and Methods: This was a cross-over randomized clinical trial on 23 overweight and obese female subjects. All patients were on a weight reducing diet. There were two trial periods for six weeks (soy drink period and cow's milk period) and a washout period for 3 weeks. In the soy drink period only one glass of soy drink (240 cc) was consumed instead of one glass of cow's milk. Results: The mean age of the patients was 22±2 years. Mean of BMI was 28.1±0.5. Weight and waist circumference did not changed significantly after the soy drink period compared to the cow's milk period. Systolic blood pressure reduced significantly following the soy drink period (mean percent change in soy drink period: -4.0±0.9 vs -1.7±0.5 in the cow's milk period; $p<0.05$). Diastolic blood pressure also reduced in the soy drink period (-0.4±0.1 vs 0.4±0.1; $p<0.05$). Conclusion: Soy drink replacement could reduce both systolic and diastolic blood pressure among overweight and obese female youths. However, this replacement had no significant results on weight and waist circumference.

Key Words: Soy drink, body mass index, waist circumference, females, blood pressure

INTRODUCTION

Obesity is associated with cardiovascular diseases, hypertension and higher risk of morbidity and mortality.[1] Diet therapy has the lowest side effects for overweight and obese patients.[2] Recently, protein intake is considered as a major role in controlling obesity.[3] High protein content of foods can reduce appetite and decrease the amount of food consumed, which is an ideal strategy for overweight and obese subjects.[4] Among vegetable proteins; soy protein, because of its special component such as specific amino acids, saponines, isoflavones and phospholipids, might have beneficial effects on weight control. Soy isoflavones have two kinds of receptors in adipose tissue and muscles. Isoflavones can have important role in fat and glucose metabolism. They can limit fat accumulation in the liver and other parts of the body then reduce the lipotoxicity and other side effects of obesity.[5] Soy protein can also reduce the appetite by increasing the amount of Cholecystokinin.[6] A recent epidemiologic study among Japanese postmenopausal women showed that higher soy product intake is associated with lower body mass index.[7] Experimental studies on rats also showed that soy consumption could reduce the size of fat mass,[8] and could decrease weight compared to casein group.[9] However, there are some clinical studies which show no significant changes on weight following soy protein intake among humans.[10,11]

Recent papers highlight that benefits of the whole soy are more than that of the soy components.[12] Whole soy have more unique effect compared to select soy components. Soy drink is similar to a whole soy item with most of the components of soy. Soy drink components such as isoflavones, essential fatty acids, phytoesterols, good fats, inositols might have beneficial effects on weight control and blood pressure management.[12] The polyphenol content of soy can affect endothelial function and then blood pressure.[13] However, few studies focused on the effects of soy drink on weight reduction or blood pressure control. A recent clinical trial revealed that soy drink consumption had the lowest effect on weight reduction compared to cow's milk or calcium supplements.[14] Another epidemiological study in a Dutch older population revealed that the type of protein is not related to the incidence of hypertension.[15] Most studies in this regard have been conducted on postmenopausal or premenopausal women and there are

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few studies on female youths. Therefore, we are going to determine the effects of soy consumption on the weight, waist circumference and blood pressure in overweight and obese female youths.

MATERIALS AND METHODS

Participants

Being in the age range of 18 to 30 and having body mass index more than 25 kg/m^2 were the inclusion criteria. Having allergy to soy product or cow's milk and not consuming soy drink or cow's milk, incidence of chronic or acute diseases which affects the adherence to research protocol or medications use were the exclusion criteria.

The study's sample size was calculated based on the formula suggested for cross-over trials: $n=[(z_{1-\alpha/2}+z_{1-\beta})^2 S]/2\Delta^2$; where α (type 1 error) was 0.05, β (type 2 error) was 0.20, S (the variance of BMI) was 4 and Δ (the difference in mean of BMI) was 1. Regarding the considered significant level in our study (α=0.05) was used in sample size formula, its related z from normal distribution is 1.96 and for considered power (1-β=0.8), its related z is 1.28. We considered BMI as the principal variable. Therefore, $n=[(1.96+1.28)^2. (4)] /^2 (1)^2=20$. Therefore, according to the formula mentioned above, 20 patients were needed for adequate power.

Thirty-four female participants volunteered to participate in the study. After measuring weight and height and calculating body mass index (BMI), we understood that all of them had BMI levels of more than 25 kg/m^2. They were not diagnosed with any specific diseases or were not on specific medications. Their biochemical blood test records showed no specific problem. Only one female was excluded because she was on medication for treating hypothyroidism. All participants provided informed written consent. This study was approved by the research council and ethics committee of Food Security Research Center, Isfahan University of Medical Sciences. This study has been registered at http://www.clinicaltrials.gov (ID number NCT01253876). We followed the CONSORT statement in writing this clinical trial manuscript.

This was a cross-over randomized clinical trial which was conducted in 2010, in Isfahan, on overweight or obese female youths. After three weeks run-in, females were randomly assigned to consume a diet containing cow's milk or a diet in which only one glass of cow's milk was substituted with soy drink; each one for six weeks. Random sequencing generated in SPSS was used to allocate females participants in a different group randomly. Participants were not blinded because they had to drink soy milk in one period of that trial and cow's milk in another period. Each patient received two diets and had a washout period for three weeks between the two periods of the trial. Therefore, measurements were obtained at baseline, after 6, 9, and 15 weeks. The randomization was conducted at the end of the run-in. All patients were on a weight reducing diet. Foods were not prepared for the patients, so, they were prescribed the diet and prepared their own meals. Only soy drink with different flavors were provided for them. Soy drink characteristics are shown in Table 1. They were asked not to change their usual physical activity level for the duration of the study. Every month patients recorded their physical activity for three days.

Diets

We prescribed two diets for each patient: 1) diet with cow's milk and 2) diet with soy drink. Both diets included macronutrient composition of 50-60% carbohydrates, 15-20% protein, <30% total fat, and <5% of caloric intake from simple sugars.

To calculate the calorie requirement of each participant, we used the equations suggested by the Institute of Medicine, Food and Nutrition Board.[16] We also provided 200 to 500 kcal/day deficit for each female participant based on their BMI range. In the soy drink period, one glass of soy drink (240 cc) was consumed instead of one glass of cow's milk (240 cc). The benefits of each diet, how to keep a food diary, and how to use an exchange list were explained to all participants by the study nutritionist. Diets were individually tailored using a calorie count system and an exchange list was given to each patient to suggest substitutions for particular food items and to calculate calories.

Patient adherence was assessed in terms of attendance at every two week visits and through analysis of the three-day food diaries. We found no significant difference between the prescribed amount and amount consumed from each of the five food groups, as derived from the food record and diet prescription.

Measurements

Participants were weighed with minimal clothes and without shoes. Weights were recorded on digital scales to the nearest 0.1 kg. Height was measured in a standing position, without shoes, using a measuring tape while shoulders were in a normal position. Waist circumference was measured in the place where the waist was narrowest over light clothing. We used a non-stretchable tape measure, without applying pressure to the body surface. Waist circumference (WC) was measured to the nearest 0.1 cm. Hip circumference was measured in the largest part of the hip over light clothing. Blood pressure was measured three times after the participants sat for 15 min. Then we reported the mean of the three times measurement.

Statistical analysis

For globally comparing means of the all variables at the end of the two different diet periods, a paired t-tests was used. The percent change for each variable was calculated by the formula (E-B/B)×100, where E was the end of

Table 1. Characteristics of the soy drink which was consumed in the present study

Nutrients and content	Amount per 100 g
Fat	1%
Carbohydrate	3.5 g
Calcium	40 mg
Na	40 mg
Protein	2 g
Sugar	2 g

treatment value and B was the baseline value. Groups were compared using the percent change in paired t-test analyses. Period effect and treatment order effects were tested using the appropriate general linear models.

All results were considered significant if the two-tailed *p*-value was <0.05. Statistical analyses were performed using SPSS for Windows version 13.0 (SPSS, Chicago IL) and SAS version 8.2 (SAS Institute Inc, 1999).

RESULTS

Of the 33 participants, 23 females completed the study. During the study one participant was diagnosed with skin problems and did not continue the study. Nine females did not follow the study protocol and therefore, their data were not available. Reasons for other patient exclusions included: not coming to the clinic (e.g. there was a great distance between the home and clinic), incomplete food and physical activity records. Participant diagram is shown in Figure 1.

The mean age of the participants was 22.08±2.71years. Participants had overweight or obesity for a mean duration of 4±0.5 years. Of the participants, 22% were married and 78% were single. None of the participants were on specific medications and none were smokers.

Nutrient contents of two diets which were analyzed from the three-day diet self-report are shown in Table2. No complications were reported from consuming soy drink.

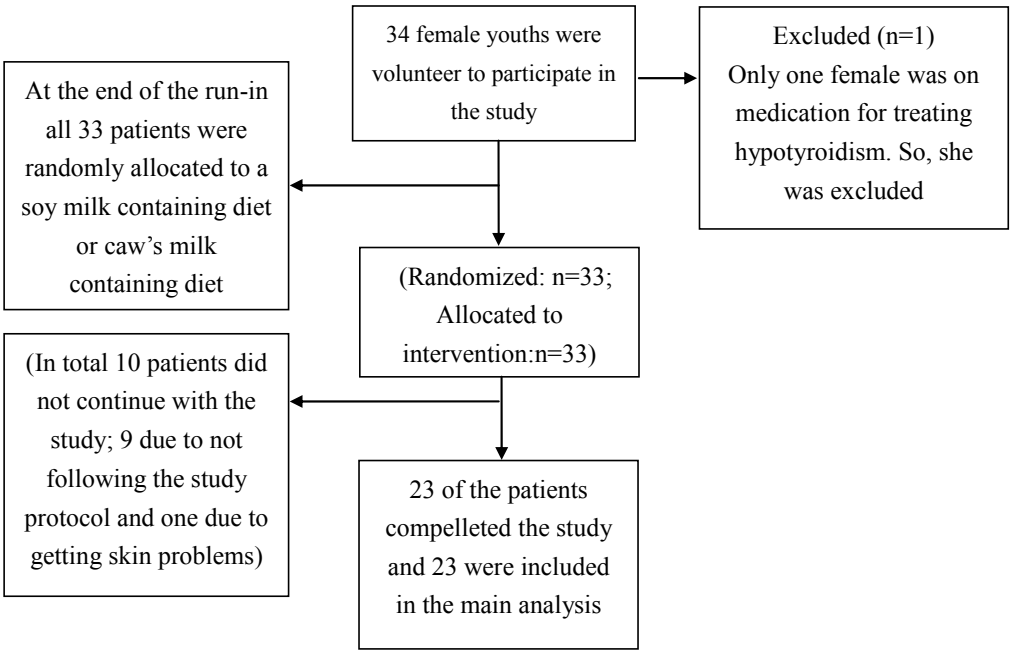

Figure 1. Participants diagram

Table 2. Macronutrients and servings of different food group intake in each dietary period

Dietary intakes (per day)	Cow's milk† (n=23)	Soy drink ‡ (n=23)	*p* §	Wash-out¶ (n=31)
Nutrients††				
Energy (Kcal)	2355±29	2391±35	0.52	2619±43
Protein (% of energy)	14.0±0.3	14.1±0.3	0.65	15.0±0.4
Total fat (% of energy)	32.7±1.2	31.7±1.2	0.39	33.0±1.6
Cholesterol (mg)	375±32	335±27	0.06	410±39
Carbohydrate (% of energy)	53.3±1.1	54.2±1.1	0.65	52.0±2
Fiber (g)	20±0.6	17.5±0.1	0.07	18±2
Food groups (servings/d)				
Fruits	6.7±0.5	5.9±0.5	0.08	4.5±0.8
Vegetable	3.6±0.3	4.0±0.4	0.17	3.0±0.2
Total grains	11.4±0.8	11.1±0.8	0.24	15.4±0.9
Dairy	3.9±0.2	3.5±0.3	0.11	2.5±0.1
Meat	6.8±0.8	6.9±0.9	0.28	6.6±0.9
Fat	2.9±0.2	3.2±0.3	0.10	4.1±0.4

†Cow's milk period: in this period patients consumed a weight reducing diet. General recommendation for macronutrient composition of the diet was: carbohydrates 50-60%; protein 15-20% and total fat <30%. The amount of simple sugar was less than 5% of the calorie intake. All the patients received 1 to 2 glass of cow's milk during this period.

‡Soy drink period: All the recommendations were the same as cow's milk period. Only one glass of soy drink was consumed instead of cow's milk.

§*P* values for differences among two periods (Paired t-test)

¶Wash-out: in this period, patients consumed the same diet they consumed before the study.

††All values are mean ± standard errors.

Table 3. The effects of two diets on anthropometric measurements and blood pressure level

Metabolic variables	Caw's milk† (n=23)	Soy drink ‡ (n=23)	*p* §
Weight			
Baseline	71.6±1.9¶	71.6±1.8	0.9
End of trial	70.0±1.9	68.5±1.8	0.8
Waist (cm)			
Baseline	88.9±1.5	88.8±1.4	0.9
End of trial	88.0±1.7	87.8±1.7	0.9
SBP (mmHg)			
Baseline	102.1±2.2	100.8±2.1	0.6
End of trial	100.0±2.1	96.0±2.0	0.08
DBP (mmHg)			
Baseline	65.6±2.2	66.3±2.0	0.7
End of trial	65.8±2.0	66.0±2.2	0.9
Hip circumference (cm)			
Baseline	104.1±1.2	104.2±1.1	0. 3
End of trial	104.0±1.1	104.0±1.1	0. 3
Body mass index (kg/m^2)			
Baseline	28.1±0.6	28.1±0.5	0. 9
End of trial	28.0±0.5	27.8±0.6	0. 7

SBP: Systolic blood pressure, DBP: Diastolic blood pressure
†Caw's milk period: In this period patients consumed a weight reducing diet. General recommendation for macronutrient composition of the diet was: carbohydrates 50-60%; protein 15-20% and total fat <30%. The amount of simple sugar was less than 5% of the calorie intake. All the patients received 1 to 2 glass of caw's milk during this period.
‡Soy drink period: All the recommendations were the same as caw's milk period. Only one glass of soy drink was consumed instead of caw's milk.
§*P* values are for comparison of two diet periods (Paired t-test)
¶All values are mean ± standard errors.

Table 4. Mean percent changes in anthropometric measures and blood pressure levels by each trial period

Variables	Caw's milk† (n=23)	Soy drink‡ (n=23)	*p* §
Weight	-2.2±0.3¶	-3.6±0.4	0.82
Waist	-1.0±0.2	-0.8±0.2	0.11
SBP	-1.7±0.5	-4.0±0.9	0.04
DBP	0.4±0.1	-0.4±0.1	0.04
Hip circumference	-0.09±0.3	-0.19±0.3	0.72
BMI	-0.3±0.1	-0.5±0.2	0.89

SBP: Systolic blood pressure, DBP: Diastolic blood pressure
†Caw's milk period: In this period patients consumed a weight reducing diet. General recommendation for macronutrient composition of the diet was: carbohydrates 50-60%; protein 15-20% and total fat <30%. The amount of simple sugar was less than 5% of the calorie intake. All the patients received 1 to 2 glass of caw's milk during this period.
‡Soy drink period: All the recommendations were the same as caw's milk period. Only one glass of soy drink was consumed instead of caw's milk.
§*p* values are for comparison of two diet periods (Paired t-test)
¶All values are mean percent change ± standard errors.

Participant's activity levels remained the same during the entire study period (Mean and SE of physical activity when on the cow's milk diet: 2.33±0.26 MET-h/d; when on the soy drink diet 2.410±0.28 MET-h/d, p=0.17).

The effects of the two diets on anthropometric measurements and blood pressure level are shown in Table 3. There were no significant differences between groups regarding anthropometric measurements and blood pressure levels at baseline and at the end of the study. Mean percent changes in anthropometric measures and blood pressure level by each trial period are presented in Table 4. No significant changes were reported regarding the anthropometric variables. Both systolic and diastolic blood pressure reduced significantly after replacement with soy drink in the diet.

DISCUSSION

The results of the present study conducted among overweight and obese female youths revealed that soy drink replacement in the diet had no significant effect on weight and waist circumference. However, soy drink consumption could reduce blood pressure significantly among these females. Few studies have focused on the female youths. In previous studies, older adults, mostly premenopausal and post menopausal women were considered as the target population in clinical trials with soy products. Several studies have assessed the effect of soy products on weight reduction in rats.[8,9,17-19] Some experimental studies have shown beneficial effects of soy replacement in this regard.[8,9,17] Beta conglycinin which is a major soy protein can embed peptides that limit lipid accu-

mulation in vitro.[20] Soy peptides may play a role on body weight regulation, possibly by increasing energy utilization.[18] Phytoesterogen content of soy might have beneficial effects on reducing fat accumulation.[21] Meal replacement diet with high soy protein drinks also has beneficial effects on weight reduction and anthropometric measures in overweight and obese subjects.[22] However, there are some studies which showed no significant results from soy consumption on anthropometric variables or fat mass reduction.[19,23]

Polyphenoles in soy have beneficial effects on controlling blood pressure.[13] Serum nitric oxide level increases after soy product consumption which is related to blood pressure reduction.[24] Results from observational studies also revealed an inverse association between plant protein intake and blood pressure.[25] ACE inhibitory peptides, derived from a multitude of plant proteins such as soy can be enzymatically released from precursor proteins in vitro and in vivo, respectively during food processing and gastrointestinal digestion. They can reduce blood pressure by limiting the vasoconstrictory effects of Angiotensin II and potentiating the vasodilatory effects of Bradykinin. Soy milk is a source of these peptides.[26] Biologically active peptides in soy are considered to promote diverse activities, including antioxidant, antithrombotic and antihypertensive actions. By modulating and improving physiological functions, bioactive peptides may provide new therapeutic applications for the prevention or treatment of hypertension.[27] Most studies have focused on consuming the soy protein (only some components of soy) and few studies have considered all parts of the soy and focus on whole soy. Recent publications showed higher beneficial effects from soy nut or soy milk which were more complete forms.[12] Assessing the effects of whole soy with all constituents of phytoesterols, essential fats, plant amino acids, isoflavones might have more benefits. Even trials with soy milk had better results on hypertension compared to supplements of isoflavones or repacing the soy protein in the diet.[28] It seems that the purified phytoestrogens or isolated soy protein alone are not as effective as the combination of soy protein, fatty acids, and phytoestrogens together.[29] Recent studies mentioned different effects of different soy products. Cassidy *et al.* compared the pharmacokinetics of isoflavones from soymilk (liquid matrix) with those of textured vegetable protein (solid matrix) and found that soymilk yielded higher maximal plasma isoflavone concentrations and total areas under the curve, despite equivalent doses per kilogram body weight, which implied food matrix or compositional effects. [30] However, one clinical trial showed that consumption of differently processed soy-based products has no major clinical effect on cardiovascular disease risk factors, including peripheral endothelial function.[31] Our previous study revealed that a diet full of fiber and vegetable, fruit, whole grain and dairy could have beneficial effects on the weight and blood pressure,[32] these sources of fiber also have high amount of phytoesterogen and antioxidant which might be responsible in the weight reducing effect and blood pressure control. In the present study, phytoesterogen and isoflavones might also have a role in controlling the blood pressure.

In the present study, female participants were from a young age group. Although they were overweight or obese, they were not hypertensive cases. Our study suggests that soy drink could reduce the blood pressure even in this young population with normal blood pressure level.

Calorie restriction in the present study was in the range of 200 to 500 kcal per day which was a small to moderate calorie restriction. Soy drink replacement did not enhance weight loss or waist reduction. Only one glass of soy drink was recommended in the soy drink period. Limited soy drink intake and short trial duration might be related to this non-significant result.

Cross-over design of the study was a positive point of the study. Furthermore, among different soy products, soy drink was chosen for this intervention.

In the present study we just recommended the food items to b consumed and only soy drink was provided to the participants. So, pre-prepared food was not given to participants. In the studies where food was given to participants, researchers could control exactly what the subjects ate. In our study, dietary intake was assessed by analyzing each patient's self-reported food record. Although the diets in our study may not have been followed as carefully as in trials where prepared food was provided, our results suggest that even imperfect compliance could have benefits on blood pressure. This was an open labeled study and the type of milk consumed was not blinded. This might have some biases on the results of the study. We had to give the pockets of soy drink or cow's milk which had a label on it. This open labeled characteristic of the present study should be considered as a limitation. The rate of non-compliance was also a limitation in the present study. Reasons for other patient exclusions included not coming to the clinic (e.g. there was a great distance between the home and clinic) incomplete food and physical activity records. About one-third of study subjects were lost to follow-up, which might be considered as another limitation of the present study. However, we analyzed data on 23 subjects (remained subjects) which was higher than the number needed for this study, according to the results of the formula for calculating the number of participants, for adequate power. Furthermore, this was a cross-over trial and cross-over trials are usually carried out over a longer time period, which results in a greater number of patient exclusions. Due to limited budget, we could not add the biochemical indices in this project. However, our trial should have good external validity since we have conducted this study on a sample of overweight or obese young females without any specific disorder.

In conclusion, soy drink replacement in the diet of overweight and obese female youths could reduce blood pressure values significantly. However, anthropometric measures did not change significantly following this replacement.

AUTHOR DISCLOSURES

None of the authors had any conflict of interest.

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Original Article

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豆漿對於過重和肥胖年輕女性的體位及血壓的影響

背景：豆漿對於肥胖和過重的人的體位和血壓值可能有益處，所以本篇研究探討豆漿對於過重和肥胖的年輕女性之體重、腰圍和血壓的影響。方法：總共有23 位過重和肥胖女性參與交叉的隨機臨床試驗。所有受試者皆採用減肥飲食。每回試驗期(食用豆漿或牛奶)為六週，兩期中間有三週的廓清期。食用豆漿期時，僅有一杯牛奶以一杯豆漿(240 cc)取代。結果：受試者平均年齡 22±2 歲，BMI 平均值為 28.1±0.5。比較豆漿期和牛奶期，體重和腰圍並沒有顯著差異。豆漿期時，受試者收縮壓有顯著下降(改變的百分率：豆漿期-4.0±0.9 比上牛奶期-1.7±0.5；p<0.05)。舒張壓在豆漿期時也顯著下降(-0.4 ±0.1 比上 0.4±0.1; p<0.05)。結論：以豆漿取代牛奶可以改善過重和肥胖年輕女性之收縮壓和舒張壓。然而，對於體重和腰圍並沒有明顯的效果。

關鍵字：豆漿、身體質量指數、腰圍、女性、血壓